

appropriate in seeking this information.

(c) *Determination and notice by CMS—*

(1) *Determination.* (i) On the basis of the investigation, CMS determines whether the HMO has failed to comply with any of the assurances it gave under subpart D of this part.

(ii) CMS publishes in the FEDERAL REGISTER a notice of each determination of non-compliance.

(2) *Notice of determination: Corrective action.* (i) CMS gives the HMO written notice of the determination.

(ii) The notice specifies the manner in which the HMO has not complied with its assurances and directs the HMO to initiate the corrective action that CMS considers necessary to bring the HMO into compliance.

(iii) The HMO must initiate this corrective action within 30 days of the date of the notice from CMS, or within any longer period that CMS determines to be reasonable and specifies in the notice. The HMO must carry out the corrective action within the time period specified by CMS in the notice.

(iv) The notice may provide the HMO an opportunity to submit, for CMS's approval, proposed methods for achieving compliance.

(d) *Remedy: Revocation of qualification.* If CMS determines that a qualified HMO has failed to initiate or to carry out corrective action in accordance with paragraph (c)(2) of this section—
(1) CMS revokes the HMO's qualification and notifies the HMO of this action.

(2) In the notice, CMS provides the HMO with an opportunity for reconsideration of the revocation, including, at the HMO's election, a fair hearing.

(3) The revocation of qualification is effective on the tenth calendar day after the day of the notice unless CMS receives a request for reconsideration by that date.

(4) If after reconsideration CMS again determines to revoke the HMO's qualification, this revocation is effective on the tenth calendar day after the date of the notice of reconsidered determination.

(5) CMS publishes in the FEDERAL REGISTER each determination it makes under this paragraph (d).

(6) A revocation under this paragraph (d) has the effect described in §417.164.

(e) *Notice by the HMO.* Within 15 days after the date CMS issues a notice of revocation, the HMO must prepare a notice that explains, in readily understandable language, the reasons for the determination that it is not a qualified HMO, and send the notice to the following:

(1) The HMO's enrollees.

(2) Each employer or public entity that has offered enrollment in the HMO in accordance with subpart E of this part.

(3) Each lawfully recognized collective bargaining representative or other representative of the employees of the employer or public entity.

(f) *Reimbursement of enrollees for services improperly denied, or for charges improperly imposed.* (1) If CMS determines, under paragraph (c)(1) of this section, that an HMO is out of compliance, CMS may require the HMO to reimburse its enrollees for the following—

(i) Expenses for basic or supplemental health services that the enrollee obtained from other sources because the HMO failed to provide or arrange for them in accordance with its assurances.

(ii) Any amounts the HMO charged the enrollee that are inconsistent with its assurances. (Rules applicable to charges for all enrollees are set forth in §§417.104 and 417.105. The additional rules applicable to Medicare enrollees are in §415.454.)

(2) This paragraph applies regardless of when the HMO failed to comply with the appropriate assurances.

(g) *Remedy: Civil suit—(1) Applicability.* This paragraph applies to any HMO or other entity to which a grant, loan, or loan guarantee was awarded, as set forth in subpart V of this part, on the basis of its assurances regarding the furnishing of basic and supplemental services or its operation and organization, as the case may be.

(2) *Basis for action.* If CMS determines that the HMO or other entity has failed to initiate or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, CMS may bring civil action in the U.S. district court for the district in which the HMO or other entity is located, to enforce

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compliance with the assurances it gave in applying for the grant, loan, or loan guarantee.

[59 FR 49841, Sept. 30, 1994]

§ 417.164 Effect of revocation of qualification on inclusion in employee's health benefit plans.

When an HMO's qualification is revoked under § 417.163(d), the following rules apply:

(a) The HMO may not seek inclusion in employees health benefits plans under subpart E of this part.

(b) Inclusion of the HMO in an employer's health benefits plan—

(1) Is disregarded in determining whether the employer is subject to the requirements of subpart E of this part; and

(2) Does not constitute compliance with subpart E of this part by the employer.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

§ 417.165 Reapplication for qualification.

An entity whose qualification as an HMO has been revoked by CMS for purposes of section 1310 of the PHS Act may, after completing the corrective action required under § 417.163(c)(2), reapply for a determination of qualification in accordance with the procedures specified in subpart D of this part.

[43 FR 32255, July 25, 1978. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38078, July 15, 1993]

§ 417.166 Waiver of assurances.

(a) *General rule.* CMS may release an HMO from compliance with any assurances the HMO gives under subpart D of this part if—

(1) The qualification requirements are changed by Federal law; or

(2) The HMO shows good cause, consistent with the purposes of title XIII of the PHS Act.

(b) *Basis for finding of good cause.* (1) Grounds upon which CMS may find good cause include but are not limited to the following:

(i) The HMO has filed for reorganization under Federal bankruptcy provisions and the reorganization can only

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be approved with the waiver of the assurances.

(ii) State laws governing the entity have been changed after it signed the assurances so as to prohibit the HMO from being organized and operated in a manner consistent with the signed assurances.

(2) Changes in State laws do not constitute good cause to the extent that the changes are preempted by Federal law under section 1311 of the PHS Act.

(c) *Consequences of waiver.* If CMS waives any assurances regarding compliance with section 1301 of the PHS Act, CMS concurrently revokes the HMO's qualification unless the waiver is based on paragraph (a)(1) of this section.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

Subparts G–I [Reserved]

Subpart J—Qualifying Conditions for Medicare Contracts

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.400 Basis and scope.

(a) *Statutory basis.* The regulations in this subpart implement section 1876 of the Act, which authorizes Medicare payment to HMOs and CMPs that contract with CMS to furnish covered services to Medicare beneficiaries.

(b) *Scope.* (1) This subpart sets forth the requirements an HMO or CMP must meet in order to enter into a contract with CMS under section 1876 of the Act. It also specifies the procedures that CMS follows to evaluate applications and make determinations.

(2) The rules for payment to HMOs and CMPs are set forth in subparts N, O, and P of this part.

(3) The rules for HCPP participation in Medicare under section 1833(a)(1)(A) of the Act are set forth in subpart U of this part.

[60 FR 45675, Sept. 1, 1995]

§ 417.401 Definitions.

As used in this subpart and subparts K through R of this part, unless the context indicates otherwise—

Adjusted average per capita cost (AAPCC) means an actuarial estimate made by CMS in advance of an HMO's or CMP's contract period that represents what the average per capita cost to the Medicare program would be for each class of the HMO's or CMP's Medicare enrollees if they had received covered services other than through the HMO or CMP in the same geographic area or in a similar area.

Adjusted community rate (ACR) is the equivalent of the premium that a risk HMO or CMP would charge Medicare enrollees independently of Medicare payments if the HMO or CMP used the same rates it charges non-Medicare enrollees for a benefit package limited to covered Medicare services.

Arrangement means a written agreement between an HMO or CMP and another entity, under which—

(1) The other entity agrees to furnish specified services to the HMO's or CMP's Medicare enrollees;

(2) The HMO or CMP retains responsibility for the services; and

(3) Medicare payment to the HMO or CMP discharges the beneficiary's obligation to pay for the services.

Benefit stabilization fund means a fund established by CMS, at the request of a risk HMO or CMP, to withhold a portion of the per capita payments available to the HMO or CMP and pay that portion in a subsequent contract period for the purpose of stabilizing fluctuations in the availability of the additional benefits the HMO or CMP provides to its Medicare enrollees.

Cost contract means a Medicare contract under which CMS pays the HMO or CMP on a reasonable cost basis.

Cost HMO or CMP means an HMO or CMP that has in effect a cost contract with CMS under section 1876 of the Act and subpart L of this part.

Demonstration project means a demonstration project under section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 (note)), relating to the provision of services for which payment is made under Medicare on a prospectively determined basis.

Emergency services means covered inpatient or outpatient services that are furnished by an appropriate source

other than the HMO or CMP and that meet the following conditions:

(1) Are needed immediately because of an injury or sudden illness.

(2) Are such that the time required to reach the HMO's or CMP's providers or suppliers (or alternatives authorized by the HMO or CMP) would mean risk of permanent damage to the enrollee's health.

Once initiated, the services continue to be considered emergency services as long as transfer of the enrollee to the HMO's or CMP's source of health care or authorized alternative is precluded because of risk to the enrollee's health or because transfer would be unreasonable, given the distance and the nature of the medical condition.

Geographic area means the area found by CMS to be the area within which the HMO or CMP furnishes, or arranges for furnishing, the full range of services that it offers to its Medicare enrollees.

Medicare enrollee means a Medicare beneficiary who has been identified on CMS records as an enrollee of an HMO or CMP that has a contract with CMS under section 1876 of the Act and subpart L of this part.

New Medicare enrollee means a Medicare beneficiary who—

(1) Enrolls with an HMO or CMP after the date on which the HMO or CMP first enters into a risk contract under subpart L of this part; and

(2) Was not enrolled with the HMO or CMP at the time he or she became entitled to benefits under Part A or eligible to enroll in Part B of Medicare.

Risk contract means a Medicare contract under which CMS pays the HMO or CMP on a risk basis for Medicare covered services.

Risk HMO or CMP means an HMO or CMP that has in effect a risk contract with CMS under section 1876 of the Act and subpart L of this part.

Urgently needed services means covered services that are needed by an enrollee who is temporarily absent from the HMO's or CMP's geographic area and that—

(1) Are required in order to prevent serious deterioration of the enrollee's health as a result of unforeseen injury or illness; and

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(2) Cannot be delayed until the enrollee returns to the HMO's or CMP's geographic area.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 51986, Oct. 17, 1991; 58 FR 38072, July 15, 1993; 60 FR 45675, Sept. 1, 1995]

§ 417.402 Effective date of initial regulations.

(a) The changes made to section 1876 of the Act by section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 became effective on February 1, 1985, the effective date of the initial implementing regulations.

(b) No new cost plan contracts are accepted by CMS. CMS will, however, accept and approve applications to modify cost plan contracts in order to expand service areas, provided they are submitted on or before September 1, 2006, and CMS determines that the organization continues to meet regulatory requirements and the requirements in its cost plan contract. Section 1876 cost plan contracts will not be extended or renewed beyond December 31, 2007, where conditions in paragraph (c) of this section are present.

(c) *Mandatory HMO or CMP and contract non-renewal or service area reduction.* CMS will non-renew all or a portion of an HMO's or CMP's contracted service area using procedures in § 417.492(b) and § 417.494(a) for any period beginning on or after January 1, 2013, where—

(1) There were two or more coordinated care plan-model MA regional plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph(c)(3) of this section; or

(2) There were two or more coordinated care plan-model MA local plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section.

(3) *Minimum enrollment requirements.* With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area (MSA) with a population of more than 250,000 and counties contiguous to the MSA that are not in another MSA with a

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population of more than 250,000, 5000 enrolled individuals. If the service area includes a portion in more than one MSA with a population of more than 250,000, the minimum enrollment determination is made with respect to each such MSA and counties contiguous to the MSA that are not in another MSA with a population of more than 250,000.

[63 FR 35066, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4713, Jan. 28, 2005; 73 FR 54248, Sept. 18, 2008; 76 FR 21560, Apr. 15, 2011; 76 FR 54633, Sept. 1, 2011]

§ 417.404 General requirements.

(a) In order to contract with CMS under the Medicare program, an entity must—

(1) Be determined by CMS to be an HMO or CMP (in accordance with §§ 117.142 and 417.407, respectively); and

(2) Comply with the contract requirements set forth in subpart L of this part.

(b) CMS enters into or renews a contract only if it determines that action would be consistent with the effective and efficient implementation of section 1876 of the Act.

[60 FR 45675, Sept. 1, 1995]

§ 417.406 Application and determination.

(a) *Responsibility for making determinations.* CMS is responsible for determining whether an entity meets the requirements to be an HMO or CMP.

(b) *Application requirements.* (1) The application requirements for HMOs are set forth in § 417.143.

(2) The requirements of § 417.143 also apply to CMPs except that there are no application fees.

(c) *Determination.* CMS uses the procedures set forth in § 417.144(a) through (d) to determine whether an entity is an HMO or CMP.

(d) *Oversight of continuing compliance.* (1) CMS oversees an entity's continued compliance with the requirements for an HMO as defined in § 417.1 or for a CMP as set forth in § 417.407.

(2) If an entity no longer meets those requirements, CMS terminates the contract of that entity in accordance with § 417.494.

[60 FR 45675, Sept. 1, 1995]

§ 417.407 Requirements for a Competitive Medical Plan (CMP).

(a) *General rule.* To qualify as a CMP, an entity must be organized under the laws of a State and must meet the requirements of paragraphs (b) through (f) of this section.

(b) *Required services*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, the entity furnishes to its enrollees at least the following services:

(i) Physicians' services performed by physicians.

(ii) Laboratory, x-ray, emergency, and preventive services.

(iii) Out-of-area coverage.

(iv) Inpatient hospital services.

(2) Exception for Medicaid prepayment risk contracts. An entity that had, before 1970, a Medicaid prepayment risk contract that did not include provision of inpatient hospital services is not required to provide those services.

(c) *Compensation for services.* The entity receives compensation (except for deductibles, coinsurance, and copayments) for the health care services it provides to enrollees on a periodic, prepaid capitation basis regardless of the frequency, extent, or kind of services provided to any enrollee.

(d) *Source of physicians' services.* The entity provides physicians' services primarily through—

(1) Physicians who are employees or partners of the entity; or

(2) Physicians or groups of physicians (organized on a group or individual practice basis) under contract with the entity to provide physicians' services.

(e) *Assumption of financial risk.* The rules set forth in §417.120(b) for HMOs apply also to CMPs except that reference to "basic services" must be read as reference to the required services listed in paragraph (b) of this section.

(f) *Protection of enrollees.* The entity provides adequately against the risk of insolvency by meeting the requirements of §§ 417.120(a) and 417.122 for protection of enrollees against loss of benefits and liability for payment of any fees that are the legal responsibility of the entity.

[60 FR 45675, Sept. 1, 1995]

§ 417.408 Contract application process.

(a) *Contents of application.* (1) The application for a contract must include supporting information in the form and detail required by CMS. (2) Whenever feasible, CMS exempts the HMO or CMP from resubmittal of information it has already submitted to CMS in connection with a determination made under the provisions of §417.406.

(b) *Approval of application.* (1) If CMS approves the application, it gives written notice to the HMO or CMP, indicating that it meets the requirements for either a risk or reasonable cost contract or only for a reasonable cost contract.

(2) If the HMO or CMP is dissatisfied with a determination that it meets the requirements only for a reasonable cost contract, it may request reconsideration in accordance with the procedures specified in subpart R of this part.

(c) *Denial of application.* If CMS denies the application, it gives written notice to the HMO or CMP indicating—

(1) That it does not meet the contract requirements under section 1876 of the Act;

(2) The reasons why the HMO or CMP does not meet the contract requirements; and

(3) The HMO's or CMP's right to request reconsideration in accordance with the procedures specified in subpart R of this part.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§ 417.410 Qualifying conditions: General rules.

(a) *Basic requirement.* In order to qualify for a contract with CMS under this subpart, an HMO or CMP must demonstrate its ability to enroll Medicare beneficiaries and other individuals and groups and to deliver a specified comprehensive range of high quality services efficiently, effectively, and economically to its Medicare enrollees.

(b) *Other qualifying conditions.* An HMO or CMP must meet qualifying conditions that pertain to operating experience, enrollment, range of services, furnishing of services, and a quality assurance program.

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(c) *Standards.* Generally, each qualifying condition is interpreted by a series of standards that are used in surveying an HMO or CMP to determine its qualifications for a Medicare contract.

(d) *Application of standards.* Application of the standards enables the surveyor to determine—

- (1) The HMO's or CMP's activities;
- (2) The extent to which the HMO or CMP complies with each condition;
- (3) The nature and extent of any deficiencies; and
- (4) The need for improvement if CMS should enter into a contract with the HMO or CMP.

(e) *Requirements for a risk contract.* An HMO or CMP may enter into a risk contract with CMS if it—

- (1) Meets all the applicable requirements in the statute and regulations;
- (2) Has at least 5,000 enrollees or 1,500 enrollees if it serves a primarily rural area as defined in § 417.413(b)(3);
- (3) Has at least 75 Medicare enrollees or has an acceptable plan to achieve this Medicare membership within 2 years;
- (4) Satisfies CMS that it can bear the potential losses of a risk contract; and
- (5) Has not previously terminated or failed to renew a risk contract within the preceding 5 years, unless CMS determines that circumstances warrant special consideration.

(f) *Requirements for a reasonable cost contract.* An HMO or CMP may enter into a reasonable cost contract if it meets one of the following:

- (1) The HMO or CMP qualifies for a risk contract, but chooses a reasonable cost contract.
- (2) The HMO or CMP meets the conditions for entering into a risk contract specified in paragraph (e) of this section except that CMS does not judge the HMO or CMP capable of bearing the potential losses of a risk contract.

(g) Regulations on reasonable cost and risk reimbursement are set forth in subparts O and P of this part.

[50 FR 20570, May 17, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

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§ 417.412 Qualifying condition: Administration and management.

The HMO or CMP must demonstrate that it—

- (a) Has sufficient administrative capability to carry out the requirements of the contract; and
- (b) Does not have any agents or management staff or persons with ownership or control interests who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, or social service programs under title XX of the Act.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§ 417.413 Qualifying condition: Operating experience and enrollment.

(a) *Condition.* The HMO or CMP must demonstrate that it has operating experience and an enrolled population sufficient to provide a reasonable basis for establishing a prospective per capita reimbursement rate or a reasonable cost reimbursement rate, as appropriate.

(b) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a risk basis.* To be eligible to contract on a risk basis—

(1) A nonrural HMO or CMP must currently have the following:

- (i) At least 5,000 enrollees; and
- (ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(2) A rural HMO or CMP must currently have—

- (i) At least 1,500 enrollees; and
- (ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(3) For purposes of this paragraph, an HMO or CMP is considered rural if at least 50 percent of its enrollees reside in nonmetropolitan areas. A nonmetropolitan area is an area—

(i) No part of which is within a metropolitan statistical area (MSA) as designated by the Executive Office of Management and Budget; and

(ii) That does not contain a city whose population exceeds 50,000 individuals.

(4) A subdivision or subsidiary of an HMO or CMP that meets the requirements of paragraph (b)(1) or (b)(2) of this section need not demonstrate that it meets those requirements as an independent unit if the HMO or CMP assumes responsibility for the financial risk, and adequate management and supervision of health care services furnished by its subdivision or subsidiary.

(c) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a cost basis.* To be eligible to contract on a reasonable cost basis, an HMO or CMP must currently have enrollees sufficient in number to provide a reasonable basis for entering into a contract, as follows:

(1) At least 1,500 enrollees.

(2) At least 75 Medicare enrollees, or a plan acceptable to CMS for achieving—

(i) A Medicare enrollment of 75 within 2 years from the beginning of its initial contract period; and

(ii) At least 250 Medicare enrollees by the beginning of its fourth contract period.

(d) *Standard: Composition of enrollment—(1) Requirement.* Except as specified in paragraphs (d)(2) and (e) of this section, not more than 50 percent of an HMO's or CMP's enrollment may be Medicare beneficiaries.

(2) *Waiver of composition of enrollment standard.* CMS may waive compliance with the requirements of paragraph (d)(1) of this section if the HMO or CMP has made and is making reasonable efforts to enroll individuals who are not Medicare beneficiaries and it meets one of the following requirements:

(i) The HMO or CMP serves a geographic area in which Medicare beneficiaries and Medicaid beneficiaries constitute more than 50 percent of the population. (CMS does not grant a waiver that would permit the percentage of Medicare and Medicaid enrollees to exceed the percentage of Medicare beneficiaries and Medicaid beneficiaries in the population of the geographic area.)

(ii) The HMO or CMP is owned and operated by a government entity. The waiver may be for a period up to three

years after the date the HMO or CMP first enters into a contract under this subpart, and may not be extended.

(iii) The HMO or CMP requests waiver of the composition rule because it is in the public interest. The organization provides documentation that supports one of the following:

(A) The organization serves a medically underserved rural or urban area.

(B) The organization demonstrates a long-term business and community service commitment to the area.

(C) The organization believes that a waiver is necessary to promote managed care choices in an area with limited or no managed care choices.

(3) *Waiver granted on or before October 21, 1986.* An HMO or CMP (or a successor HMO or CMP) that as of October 21, 1986, had been granted an exception, waiver, or modification of the requirements of paragraph (d)(1) of this section, but that does not meet the requirements of paragraph (d)(2) of this section, must make (and throughout the period of the exception, waiver, or modification continue to make) reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by CMS.

(i) If CMS determines that the HMO or CMP has complied, or made significant progress toward compliance, with the approved schedule, and that an extension is in the best interest of the Medicare program, CMS may extend the waiver of modification.

(ii) If CMS determines that the HMO or CMP has not complied with the approved schedule, CMS may apply the sanctions described in paragraphs (d)(6) and (d)(7) of this section.

(4) *Basis for application of sanctions.* CMS may, as an alternative to contract termination, apply the sanctions specified in paragraph (d)(6) of this section if CMS determines that the HMO or CMP is not complying with the requirements in paragraphs (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(5) *Notice of sanction.* Before applying the sanctions specified in paragraph (d)(6) of this section, CMS sends a written notice to the HMO or CMP stating the proposed action and its basis. CMS gives the HMO or CMP 15 days after

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the date of the notice to provide evidence establishing the HMO's or CMP's compliance with the requirements in paragraph (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(6) *Sanctions.* If, following review of the HMO's or CMP's timely response to CMS's notice, CMS determines that an HMO or CMP does not comply with the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section, CMS may apply either of the following sanctions:

(i) Require the HMO or CMP to stop accepting new enrollment applications after a date specified by CMS.

(ii) Deny payment for individuals who are formally added or “accreted” to CMS's records as Medicare enrollees after a date specified by CMS.

(7) *Termination by CMS.* In addition to the sanctions described in paragraph (d)(6) of this section, CMS may decline to renew an HMO's or CMP's contract in accordance with § 417.492(b), or terminate its contract in accordance with § 417.494(b) if CMS determines that the HMO or CMP no longer substantially meets the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section.

(8) *Termination of composition standard.* The 50 percent composition of Medicare beneficiaries terminates for all managed care plans on December 31, 1998.

(e) *Standard: Open enrollment.* (1) Except as specified in paragraph (e)(2) of this section, an HMO or CMP must enroll Medicare beneficiaries on a first-come, first-served basis to the limit of its capacity and provide annual open enrollment periods of at least 30 days duration for Medicare beneficiaries.

(2) CMS may waive the requirement of paragraph (e)(1) of this section if compliance would prevent compliance with the limitation on enrollment of Medicare beneficiaries and Medicaid beneficiaries (paragraph (d) of this section) or result in an enrollment substantially nonrepresentative of the population of the HMO's or CMP's geographic area. The enrollment would be “substantially nonrepresentative” if the proportion of a subgroup to the total enrollment exceeded, by 10 percent or more, its proportion of the population in the HMO's or CMP's geographic area, as shown by census data

or other data acceptable to CMS. For purposes of this paragraph, a subgroup means a class of Medicare enrollees as defined in § 417.582.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995; 63 FR 35066, June 26, 1998]

§ 417.414 Qualifying condition: Range of services.

(a) *Condition.* The HMO or CMP must demonstrate that it is capable of delivering to Medicare enrollees the range of services required in accordance with this section.

(b) *Standard: Range of services furnished by eligible HMOs or CMPs—*(1) *Basic requirement.* Except as specified in paragraph (b)(3) of this section, an HMO or CMP must furnish to its Medicare enrollees (directly or through arrangements with others) all the Medicare services to which those enrollees are entitled to the extent that they are available to Medicare beneficiaries who reside in the HMO's or CMP's geographic area but are not enrolled in the HMO or CMP.

(2) *Criteria for availability.* The services are considered available if—

(i) The sources are located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to sources outside that geographic area.

(3) *Exception for hospice care.* An HMO or CMP is not required to furnish hospice care as described in part 418 of this chapter. However, HMOs or CMPs must inform their Medicare enrollees about the availability of hospice care if—

(i) A hospice participating in Medicare is located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to hospices outside the geographic area.

(c) *Standard: Financial responsibility for services furnished outside the HMO or CMP.* (1) An HMO or CMP must assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services (as defined in § 417.401) that are obtained by its Medicare enrollees from providers and suppliers outside the HMO or CMP even in the absence of the HMO's or CMP's prior approval.

(2) An HMO or CMP must assume financial responsibility for services that the Medicare enrollee attempted to obtain from the HMO or CMP, but that the HMO or CMP failed to furnish or unreasonably denied, and that are found, upon appeal by the enrollee under subpart Q of this part, to be services that the enrollee was entitled to have furnished to him or her by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§417.416 Qualifying condition: Furnishing of services.

(a) *Condition.* The HMO or CMP must furnish the required services to its Medicare enrollees through providers and suppliers that meet applicable Medicare statutory definitions and implementing regulations. The HMO or CMP must also ensure that the required services, additional services, and any other supplemental services for which the Medicare enrollee has contracted are available and accessible and are furnished in a manner that ensures continuity.

(b) *Standard: Conformance with conditions of participation, conditions for coverage, and conditions for certification.* (1) Hospitals, SNFs, HHAs, CORFs, and providers of outpatient physical therapy or speech-language pathology services must meet the applicable conditions of participation in Medicare, as set forth elsewhere in this chapter.

(2) Suppliers must meet the conditions for coverage or conditions for certification of their services, as set forth elsewhere in this chapter.

(3) If more than one type of practitioner is qualified to furnish a particular service, the HMO or CMP may select the type of practitioner to be used.

(c) *Standard: Physician supervision.* The HMO or CMP must provide for supervision by a physician of other health care professionals who are directly involved in the provision of health care as generally authorized under section 1861 of the Act. Except as specified in paragraph (d) of this section, with respect to medical services furnished in an HMO's or CMP's clinic or the office of a physician with whom

the HMO or CMP has a service agreement, the HMO or CMP must ensure that—

(1) Services furnished by paramedical, ancillary, and other nonphysician personnel are furnished under the direct supervision of a physician;

(2) A physician is present to perform medical (as opposed to administrative) services whenever the clinics or offices are open; and

(3) Each patient is under the care of a physician.

(d) *Exceptions to physician supervision requirement.* The following services may be furnished without the direct personal supervision of a physician:

(1) Services of physician assistants and nurse practitioners (as defined in §491.2 of this chapter), and the services and supplies incident to their services. The conditions for payment, as set forth in §§405.2414 and 405.2415 of this chapter for services furnished by rural health clinics and Federally qualified health centers, respectively, also apply when those services are furnished by an HMO or CMP.

(2) When furnished by an HMO or CMP, services of clinical psychologists who meet the qualifications specified in §410.71(d) of this chapter, and the services and supplies incident to their professional services.

(3) When an HMO or CMP contracts on—

(i) A risk basis, the services of a clinical social worker (as defined at §410.73 of this chapter) and the services and supplies incident to their professional services; or

(ii) A cost basis, the services of a clinical social worker (as defined in §410.73 of this chapter). Services incident to the professional services of a clinical social worker furnished by an HMO or CMP contracting on a cost basis are not covered by Medicare and payment will not be made for these services.

(e) *Standard: Accessibility and continuity.* (1) The HMO or CMP must ensure that the required services and any other services for which Medicare enrollees have contracted are accessible, with reasonable promptness, to the enrollees with respect to geographic location, hours of operation, and provision